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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,568	09/15/2003	Steven Z. Wu	50623.335	2840

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EXAMINER	
SHEIKH, HUMERA N	
ART UNIT	PAPER NUMBER
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/663,568	WU ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25, 27-32 and 34-37* is/are pending in the application.

4a) Of the above claim(s) *36 and 37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25, 27-32, 34 and 35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/16/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Request for Continued Examination (RCE) and Applicant's Arguments/Remarks, all filed 08/25/08 is acknowledged.

Newly submitted claims 36-37 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The originally claimed invention can be made by a different method than that of the method of claims 36-37, such as by a twin screw extrusion method.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 36 and 37 have been withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 25, 27-32 and 34-37 are pending in this action. New claims 34-37 have been added. Claims 36-37 have been withdrawn (non-elected invention). Claims 25, 27-32, 34 and 35 are being examined in this Office Action. Claims 1-24, 26 and 33 have been cancelled. Claims 25, 27-32, 34 and 35 are rejected.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 25 August 2008 has been entered.

* * * * *

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 10/16/03 has been considered by the Examiner, including the two references - B46 & B47.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 25, 28-31, 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunter *et al.* (hereinafter "Hunter") (U.S. Patent No. 5,886,026).

Hunter ('026) teaches compositions comprising anti-angiogenic factors and polymeric carriers, stents which have been coated with such compositions and methods for utilizing the

stents and compositions (see column 1, lines 15-20); (col. 4, lines 25-45); (col. 37, line 31 – col. 38, line 4) and claims. The stents may be self-expanding, balloon expandable or implanted by a change in temperature (col. 23, lines 23-42).

A wide variety of polymeric carriers may be used, including poly(ethylene vinyl acetate), poly(D, L-lactic acid), poly(glycolic acid) and copolymers of poly(caprolactone) or poly(lactic acid) with polyethylene glycol and the like and blends thereof (col. 3, lines 40-64). Polymeric carriers disclosed include both biodegradable and non-biodegradable compositions (col. 16, lines 36-62). The anti-angiogenic compositions may be linked by occlusion in the matrices of the polymer, bound by covalent linkages or encapsulated in microcapsules. In preferred embodiments, the anti-angiogenic compositions are provided in non-capsular formulations such as microspheres (ranging from nanometers to micrometers in size), as well as pastes, films and sprays (col. 16, line 63 - col. 17, line 11). The sprays may be prepared from microspheres having a size of for example, from 0.1 μm to 3μm (this range falls within and meets Applicant's claimed range of 0.5 to 2 microns in size of instant claim 29) (col. 17, lines 30-65).

In other embodiments of the invention, Hunter teaches that the polymeric carriers are adapted to contain and release a hydrophobic compound, the carrier containing the hydrophobic compound in combination with a carbohydrate, protein or polypeptide. The polymeric carrier contains or comprises regions, pockets of granules or one or more hydrophobic compounds. For example, the hydrophobic compounds may be incorporated within a matrix which contains the hydrophobic compound, followed by incorporation of the matrix within the polymeric carrier. A variety of matrices can be utilized (col. 18, lines 19-53).

Hunter teaches that the stents may be coated with the anti-angiogenic compositions in various manners, including for example: (a) by directly affixing to the stent an anti-angiogenic composition (e.g., by either spraying the stent with a polymer/drug film or by dipping the stent into a polymer/drug solution); (b) by coating the stent with a substance such as a hydrogel which will in turn absorb the anti-angiogenic composition; (c) by interweaving anti-angiogenic factor coated thread (or the polymer itself formed into a thread) into the stent structure; (d) by inserting the stent into a sleeve or mesh which is comprised of or coated with an anti-angiogenic composition; or (e) constructing the stent itself with an anti-angiogenic composition (col. 22, line 8 – col. 23, line 10).

The anti-angiogenic compositions may additionally comprise a wide variety of compounds in addition to the anti-angiogenic factor and polymeric carrier (col. 15, line 16 - col. 16, line 35).

The manufacturing process of the microspheres and the manufacturing process of the stent coating is discussed at column 45, line 31 – column 48, line 59. Also see column 54, lines 24-51, whereby preparation of control microspheres (drug absent) are discussed.

The figures demonstrate various embodiments of the invention, such as, preparations of microspheres comprising drug (i.e., paclitaxel) made in polymer blend solutions (i.e., EVA/PLA) (col. 6, line 62 - col. 11, line 54).

The instant invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, given the teachings of Hunter. Hunter teaches implantable, expandable stents coated with anti-angiogenic compositions comprising polymeric carriers. The reference teaches that various polymer carriers and blends of polymers can be

used. The reference further teaches microspheres that encapsulate the drug (i.e., paclitaxel) and polymer(s) (i.e., EVA/PLA). The reference thus discloses a multi-polymer system for use in coating stents for the treatment and therapy in embolization of blood vessels.

* * * * *

Claims 27 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunter *et al.* (hereinafter "Hunter") (U.S. Patent No. 5,886,026) as applied to claims 25, 28-31, 34 and 35 above and further in view of Wang (U.S. Patent No. 6,379,379).

Hunter ('026), as discussed above, teaches compositions comprising anti-angiogenic factors and polymeric carriers, stents which have been coated with such compositions and methods for utilizing the stents and compositions (see column 1, lines 15-20); (col. 4, lines 25-45); (col. 37, line 31 – col. 38, line 4) and claims. The stents may be self-expanding, balloon expandable or implanted by a change in temperature (col. 23, lines 23-42). Hunter teaches that for vascular stents, the composition should not render the stent thrombogenic (causing blood clots to form) or cause significant turbulence in blood flow (more than the stent itself would be expected to cause if it was *uncoated*) (see col. 23, lines 2-10).

Hunter does not that their coating layer is *free from* any therapeutic substances.

Wang ('379) teaches a stent that includes a polymeric coating or coating(s) on one or both end portions of the stent (see Abstract); (col. 1, line 10 - col. 3, line 17). The coating may be used as a drug delivery system to treat restenosis, whereby the drugs include radiochemicals to irradiate and prohibit tissue growth (col. 5, lines 32-46). Wang teaches that the stent can have

multiple layers of different polymers with the same or different drugs. For example, the stent can have two layers of the same polymer coating (18) with one layer with drug and another layer *without* drugs (col. 6, lines 24-30); (col. 4, lines 46-64).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate coatings that are free of active substance, as taught by Wang within the methods, compositions and devices taught by Hunter. One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Wang explicitly teaches that their stents can have multiple layers of the same polymer coating, whereby one layer has drug incorporated into it, while the other layer is devoid of drug(s), thus providing different polymer coating layers and materials. The expected result would be an enhanced stent for the beneficial treatment of restenosis.

* * * * *

Response to Arguments

Applicant's arguments with respect to claims 25 and 27-32 have been considered but are moot in view of the new ground(s) of rejection.

* * * * *

Conclusion

--No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday-Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Humera N. Sheikh/

Primary Examiner, Art Unit 1615

hns

November 06, 2008